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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,581	11/09/2000	Ronald S. Vladyka JR.	FMC-1006US	2095

21302 7590 10/30/2002

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/30/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,581

Applicant(s)

VLADYKA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Amendment A filed August 5, 2002 has been received and entered into the record.
2. Claims 1-26 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

4. Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964) in view Erkoboni et al (US Patent No. 5,725,886) for the reasons already of record on pages 4 and 5 of the Office Action filed May 6, 2002.

Applicant's arguments filed August 5, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of the claims on the grounds that the Asgharnejad et al patent does not disclose a two step drying process as instant Claim 1 have been amended to indicate. However, this argument is not persuasive since the instant claims do not set forth a critical temperature and critical time for carrying out the drying process that is substantially different from the temperature and time used for the drying process that is disclosed in the Asgharnejad et al patent. For example, Asgharnejad et al discloses a drying procedure for the granules to remove an ethanol and water mixture that may take 24 hours. See Example 1 of the instant application wherein the granular material is subjected to drying beyond 16 hours. It is also well known in the art that ethanol will evaporate before water in a drying process to remove a solvent comprising ethanol and water. The ethanol and water mixture in the Asgharnejad et al patent embraces the polar organic solvent and water mixture of the instant claims wherein Claim 1 discloses the removal of substantially all of the polar organic solvent before removing a substantial portion of the water. Hence, the instantly claimed two step drying process appears to be only a masquerade of what will normally occur for the evaporation of a solvent mixture comprising water and a polar organic solvent, especially since no temperature and time for the drying procedure has been set

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forth in instant Claim 1. Applicants assessment of the Erkoboni et al patent in the rejection of the claims is correct. Accordingly, the rejection of Claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over the Asgharnejad et al and Erkoboni et al patents is maintained for the reasons of record.

5. Claims 14-16 and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943).

Applicants claim a porous, granulated microcrystalline cellulose having a loose bulk density of from about 0.2 g/cc to about 0.4 g/cc and a mean particle size of from about 250 microns to about 1500 microns.

The McTeigue et al patent discloses microcrystalline cellulose particles having a particle size up to about 220 microns with a particle size standard deviation of from about 75 to about 200 microns (see column 1, line 54) and bulk density at about 0.40 grams/cubic centimeters (see column 2, lines 51 and 52), which embraces the microcrystalline cellulose granules of the instant claims. The McTeigue et al patent also discloses coating compositions, which may include the polymer systems disclose in the Table at lines 40-67 of column 4. The polymer systems disclosed by McTeigue et al include coatings that are analogous to some of the hydrocolloids set forth in instant Claims 21-23. McTeigue et al further discloses preparations that involve combining coated particles with excipients, which are compressed to form tablets (see column 6, 2nd paragraph). Also see Examples 1 and 2 of the McTeigue et al patent whereby the examples disclose compositions comprising analogous microcrystalline cellulose granules, hydrocolloid, excipient and active ingredients that embraces the instantly claimed invention. Applicants amended the claims to indicate that the mean particle size of the microcrystalline cellulose is at least 250 microns. Although, the McTeigue et al patent only discloses the microcrystalline cellulose thereof as having a mean particle size up to about 220 microns, the particle size standard deviation of 200 microns that is disclosed in the McTeigue patent does suggests microcrystalline cellulose particles that have a particle size of at least 250 microns is present in the McTeigue et al patent. It is within the skill of an artisan to screen a desired microcrystalline cellulose particle size.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention to use the microcrystalline cellulose particles of the McTeigue et al patent that have a particle size of 250 microns, in view of their closely related structures and the resulting expectation of similar drug coating properties.

6. Applicant's arguments with respect to claims 14-16 and 18-26 have been considered but are moot in view of the new ground(s) of rejection.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943) as applied to claims 14-16 and 18-26 above, and further in view of Kumar (US Patent No. 6,117,451).

Applicants claim microcrystalline cellulose granules having a loose bulk density of from about 0.25 g/cc to about 0.35 g/cc.

The information disclose in the above rejection against the McTeigue et al patent is applied in the instant rejection. The instant claims differ from the McTeigue et al patent by disclosing in Claim 17 that the microcrystalline cellulose granules have a loose bulk density of from about 0.25 g/cc to about 0.35 g/cc. The Kumar patent shows that the claimed density for microcrystalline cellulose is well known in the art by disclosing a density range of 0.20 to 0.45 g/ml for the microcrystalline cellulose thereof (see column 5, lines 46-48). Accordingly, it would have been obvious to one having ordinary skill in the art to substitute the microcrystalline cellulose having a density of 0.4 g/cc of the McTeigue et al patent for the microcrystalline cellulose that comprises a density range of 0.20 to 0.45 g/ml of the Kumar patent in view of the recognition in the art, as evidenced by the Kumar patent, that microcrystalline cellulose has inherent binding and superior tableting flow properties.

Arguments

8. Applicant's arguments filed August 5, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of the claims over the McTeigue et al and Kumar patents on the grounds that the patents do not teach the granules, as claimed. However, this argument is not persuasive since there is no process step in the patents that involve spheronizing the microcrystalline cellulose.

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Also see column 2, lines 54-57 and Fig. 1 of the McTeigue et al patent whereby an irregular shape surface of the microcrystalline cellulose is indicated, which embraces microcrystalline cellulose in granular form.

Summary

9. All the pending claims are rejected.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

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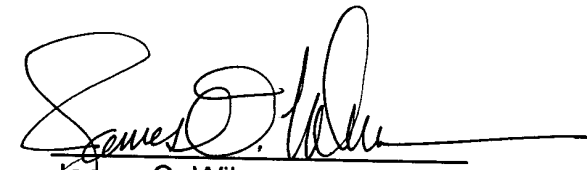
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600